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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,813	12/21/2001	Masahide Higaki	216897USOPCT	4857

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/926,813

Applicant(s)

HIGAKI ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,7-9 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,10 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

## DETAILED ACTION

### ***Election acknowledged***

1. Acknowledgement is made of an election of Groups II and the compound of claim 6, [[[2R)-5-(carboxymethoxy)-2-hydroxy-1,2,3,4-tetrahydronaphth-2-yl]methyl]N,N-diphenylcarbamate, as a single disclosed species with traverse. Applicant traversed on the ground that the search and examination can be made without a serious burden. The traverse is not persuasive due to the reasons of the record as mentioned in the previous office action. This application is national stage of PCT international application where restriction requirement is governed by PCT rule 13.1, they lack the same or corresponding special technical features.

The claimed compound is considered to be a technical feature, but not a special technical feature, because it is already known(not novel) to the art as evidenced by numerous documents(see WO97/03973, WO95/17393, WO95/24393). For example, WO' 393 teaches the very same claimed compound for different utility(i.e.arterial obstruction) than the utility recited in the instant claims. Thus, it fails to meet all the conditions for establishing "special technical features" required by Rule 13.2. It is noted that again, the express "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. (Rule 13.2).

Furthermore, it is burdensome to examine all the entire groups because a reference which anticipates the invention II would not render the inventions I, or III-V obvious, absent ancillary art, and thus, it is undue burden for examiner to perform

accurate and quality examination. Thus, the restriction requirement deems to be proper, and made FINAL.

### Status of Application

2. Claims 1-12 are pending. The elected claims 1,2,4,6,10 and 12 are presented for the examination. Non-elected claims 3, 5, 7-9, 11 are withdrawn from the consideration.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,4,6,10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi et al(WO95/24393).

The claims are drawn to a pharmaceutical composition containing a compound of formula II such as [[(2R)-5-(carboxymethoxy)-2-hydroxy-1,2,3,4-tetrahydronaphth-2-yl]methyl]N,N-diphenylcarbamate.

WO'393 teaches a pharmaceutical composition comprising naphthalene derivatives of formula I (as prostaglandin I<sub>2</sub> agonists) and a pharmaceutically acceptable salt thereof which are useful as medicaments, see abstract and page 1, lines 31 thru page 2, lines 8. It also teaches a elected species, [[(2R)-5-(carboxymethoxy)-2-hydroxy-1,2,3,4-tetrahydronaphth-2-yl]methyl]N,N-

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diphenylcarbamate and the composition containing the said species as an active agent, see claims 6-(1) and 8. Thus, all the critical elements required by the instant claims are taught by the cited reference and the claimed subject matter is not patentably distinct over the prior art of the record.

Applicant is reminded again that the claimed subject matter is directed to a pharmaceutical composition containing a compound of formula II such as [(2R)-5-(carboxymethoxy)-2-hydroxy-1,2,3,4-tetrahydronaphth-2-yl]methyl]N,N-diphenylcarbamate, where all the claimed subject matter is taught by the cited reference. It is noted that the recitation(i.e. skin ulcer or diabetic skin ulcer) in preamble has not been given patentable weight because it recites the intended use of the composition, and where the body of the claim(structure of composition) does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

### ***Double Patenting***

#### ***Duplicate claims***

4. Claims 1, 4 and 6 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 2,10 and 12, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). As

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mentioned earlier, the claims are directed to a composition where the structure of the composition are substantially same.

***Conclusion***

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,  
Patent examiner  
Art nit 1614